Review of Gene Patents and Public Health, by Geertrui Van Overwalle, ed.

BOOK REVIEW

GENE PATENTS AND PUBLIC HEALTH

By Geertrui Van Overwalle, ed.

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Gene Patents and Public Health is a compilation of articles presented at a 2005 symposium held at the University of Leuven, Belgium.[1] At the outset, Professor Geertrui van Overwalle, the editor, sets the scene by acknowledging that patents in both the healthcare and genetic contexts have a troubled history, and by noting that the book (and the symposium which preceded it) probes questions about whether diagnostic gene patents hinder public health, and whether disease gene patents are inappropriate; if the turbulent history of gene patents is any indication, then we might expect that its future will be similarly clouded. Certainly the analyses offered in *Gene Patents and Public Health* suggests that this will be the case.

Part 1 (contributions 1 to 4) considers whether gene patents for diagnostics are justified (i.e. whether diagnostic gene patents should exist). In doing so, it adopts first a practical, then a philosophical, and finally a legal perspective, the aim being to analyse the question from a variety of disciplines so as to permit a richer conclusion. Part 2 (contributions 5 to 10) proceeds from the proposition that diagnostic gene patents *are* justified and *can* be granted, and therefore considers the exercise of patent rights in light thereof. Section 1 of Part 2 (contributions 5 to 7) focuses on contractual licensing in the medical sector, whereas Section 2 (contributions 8 to 10) focuses on compulsory licensing for public health, examining the French, Swiss and Belgian models.

In "DNA Diagnostics in Practice", without actually engaging with the justification v. exercise debate that forms the structure of the book, Matthijs, a molecular geneticist, explains that there are usually a variety of methods available for analysing any given mutation-based condition, and that a genetic diagnostic test is usually not the first mechanism for diagnosing a genetically-influenced clinical condition. With some 600-900 currently known mutation-based conditions, this is an important and growing field in diagnostics. However, he reports that attempts to realise commercial success in genetic testing results in "overly profit-oriented and restrictive behaviour", and he cites the conduct of Myriad Genetics (re the BRCA breast cancer test) and Bio-Rad (re the hereditary haemochromatosis test).

In "Ethics and Patents for Genetic Diagnostic Testing", Baldwin, a philosopher, considers the social contract underlying the patent regime in the context of genetic diagnostics. He notes that the contract is premised on both rights-based and utilitarian

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[1] "Gene Patents and Public Health Symposium", 27 May 2005, Centre for Intellectual Property Rights, University of Leuven, Belgium.

approaches simultaneously, but that the publicly-minded utilitarian view is particularly important in the healthcare context because health is a fundamental aspect of human welfare and healthcare delivery is a public responsibility. While acknowledging that diagnostic patents are eligible for patenting under the European Patent Convention (1973)[2] because most tests are carried out on samples *removed* from the body, Baldwin laments that such patenting will likely obstruct other emerging technologies important to cost-effective delivery of healthcare, namely gene chips. He appropriately challenges the practice of seeking a monopoly on the use of the gene (or sequence) when obtaining a monopoly on a particular diagnostic kit that has been developed from it, and he questions the conduct of inventors who use a patent on one diagnostic invention to block the invention and marketing of diagnostics for the same condition and relying on the same gene but operative in a different way.

In "The EPC and the Granting Policy and Case Law of the EPO", Thomas, an academic and member of the EPO, reviews some of the relatively little though still contradictory jurisprudence of the EPO's Boards of Appeal. Unfortunately, Thomas's discussion has been rendered somewhat moot by the subsequent Opinion G0001/04, 16 December 2005, in which the EPO's Enlarged Board of Appeal concludes as follows:[3]

- In order that the subject-matter of a claim relating to a diagnostic method practised on a human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to: (1) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise, (2) the preceding steps which are constitutive for making that diagnosis, and (3) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.
- Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner, nor on the fact that all method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. No distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it.
- In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion "practised on the human or animal body".
- Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.

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[2] *See* Article 52(4).

[3] *See* http://legal.european-patent-office.org/dg3/pdf/g040001e.pdf [26 May 2008]. Note that van Overwalle references this Opinion at the end of that contribution.

In "Using the EPO Opposition Procedure as a Strategy Against Patents on Diagnostic Methods", Bird, a European patent attorney, reiterates the value of such procedures in light of the relatively few patent infringement and nullity cases within the member states, and briefly compares the EPO context with that of the USA. However, he concludes that, "although it is unlikely that any major changes of patent law will result directly from… oppositions, the general discussion seems to be changing informed opinion towards a harder line on the enforcement of patent law through the relevant legal institutions" (p. 82).[4]

In "Licensing in the Medical Sector", De Corte highlights the massive expense and risk associated with current pharmaceutical innovation models, and notes the consequent necessity of licensing compounds as a "Band-Aid" to filling the black holes in the existing big pharma drug pipeline.[5] He goes on to suggest that the genetic breakthroughs and imaginings of the 1980s and '90s prompted a paradigm shift in patent and licensing practices. Corporate conduct prompted by that shift has led some stakeholders to observe that patenting has become a research-stifling rather than a research-promoting tool. Now, he suggests, a second paradigm is underway, the consequences of which are not yet clear. Unfortunately, whichever paradigm is in ascendance, the promise of our new scientific knowledge has not resulted in new understandings or medicines. Ultimately, it is not clear whether licensing in the new paradigm will have the desired effect of making effective treatments a reality.

In "The Effect of Patents on Research and Development of Diagnostic Kits", Vlassak and Schüller state that the patent system has served its innovation function well until recently, and that debate persists as to the need for patents in the diagnostics field (pp. 101-102). After briefly describing that field and the types of patents that are particularly relevant thereto, they examine the patent activities of Innogenetics, a medium-sized European biopharmaceutical company which has, they argue, used its diagnostics patent portfolio as a strategic asset to advance rather than stifle further R&D, doing so by out-licensing its own products on reasonable terms so it can in-license other products so as to fill gaps in its own portfolio. They note, however, that Innogenetics' open policy is not legally mandated by patent law, which has little to say about patent licensing, but that it could be encouraged through competition law. They then call for further legislative innovation to promote such activity, suggesting exemptions and compulsory licensing, neither of which have had spectacular success to date.

In "Dealing with Patent Fragmentation: The SARS Patent Pool as a Model", Simon contributes another exemplar of how granted patents might better be exploited. Simon suggests that patent pools are an efficient means of dealing with patent right fragmentation and notes that the US Trade Commission has set guidelines for patent pools so that they might pass antitrust muster (p. 118-119). He concedes that no gene

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[4] For more on the importance of Opposition Proceedings and what the EPO might do to enhance their effectiveness, *see* S Harmon, "The Rules of Re-Engagement: The Use of Patent Proceedings To Influence the Regulation of Science ('What The Salmon Does When Comes Back Downstream')" (2006) 4 *Intellectual Property Quarterly* 378-403, and S Harmon, "From Engagement to Re-Engagement: The Expression of Moral Values in Patenting Proceedings, Present and Future" (2006) 31(5) *European Law Review* 642-666.

[5] Parenthetically, one might suggest that big pharma would be better served by changing its business model rather than further choking the innovation process with restrictive IP practices and milksop licensing arrangements.

patent pool has yet been established, but then cites the SARS situation as an ideal one to set the precedent (i.e.: the SARS corona virus was sequenced by multiple parties).

In the final contributions – Zimmeren and Requena's "Ex-Officio Licensing in the Medical Sector: The French Model", Germann's "The Swiss Approach to Compulsory Licensing for Diagnostic Products and Processes", and De Brulle, De Corte and Petit's "The Belgian Compulsory License for Public Health" (as translated and summarised by van Overwalle) – the authors review the compulsory licensing schemes in France, Switzerland and Belgium, and thereby permit a comparative assessment of these as a means of prompting movement in the unhealthy gridlock that characterises the relationship between patents and public health globally.

Although both the social contract theoretical foundation of patenting is largely supported and the validity of diagnostic gene patents is largely accepted in *Gene Patents and Public Health*, the practical realisation of an appropriate public-private balance, and the exercise of rights and enforcement of limits and exceptions are questioned. My own view, shared by Matthijs and Baldwin, is that stakeholder conduct in this field – as with many areas of activity which influence general human (or public) wellbeing – have swung in the direction of the interests of private (profit-seeking) stakeholders, with a potential for disastrous long-term consequences. One need only consider the conduct of certain actors to confirm this; of course, the Myriad (BRCA1 and BRCA2) example is widely referenced in the book (see Matthijs, Baldwin, Thomas, and Zimmeren and Requena), but others exist (eg: relating Canavan's and Alzheimer's diseases), greater reference to which would have better emphasised the widespread nature of the problems to which the book is directed.

Nonetheless, as suggest in the book, much can be done to recalibrate that relationship and redress the imbalance short of scrapping the patent regime and its complex international framework (which is a well nigh impossible proposition). In that respect, the judgment in *Kirin-Amgen Inc. et al.* v. *Hoechst Marion Roussel Ltd. et al.*[6] is of some comfort. In that case, Lord Hoffman held:

> *[77] An invention is a practical product or process, not information about the natural world. That seems to me to accord with the social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims.*

In short, patent law should not be used to prevent other inventors from making use of basic information contained in the patent (eg: DNA sequence information) to create other inventions.

Success at recalibrating the relationship would seem to depend on (1) recommitting ourselves to the rule of law as that law currently exists, and (2) legally extending the

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[6] [2004] UKHL 46.

public responsibilities of patent-holders into the post-grant period. With respect to the former, steps need to be taken to ensure that stakeholders are given the space to pursue socially valuable public health ends (eg: public health provisions and compulsory licensing provisions in instruments such as the TRIPS Agreement must be allowed to be given effect without fear of draconian legal and trade repercussions). With respect to the latter – extending the idea of the social contract into the post-grant period – one might note (as van Overwalle has) the work of the OECD and of Peter Drahos. The OECD has issued non-binding Guidelines for the Licensing of Genetic Inventions which might serve as a model for both legislation and contractual arrangements in the genetic context.[7] Drahos has conceptualised patents as temporary, duty-bearing privileges to exercise monopolies under fair and reasonable conditions.[8] Such conceptual frameworks and preliminary actions are to be encouraged and supported. Ultimately, all people (as patients) have a legitimate interest in seeking to make the patent system work properly. In the genetic and public health context, "working properly" means in large measure working for the people and the greater good, and therefore in the least restrictive way.

Gene Patents and Public Health offers the beginnings of creative ways to rectify the current controversies and quagmire. The fact that the articles are now a couple years old does not, in most cases, detract from the relevance of the book, which should be of interest to anyone concerned with patents in the healthcare context and the desire to see them work for the benefit of humanity. Having said that, given the intimate relationship between wellbeing, healthcare and ethics, and the growing dialogue concerning the interaction of patents and morality, I would have liked a greater contribution from the ethical perspective. As noted by Baldwin (p. 48), the range of ethical issues raised by the topic is much broader than that actually addressed (eg: the ethics of patenting inventions contributed to by public funds, the ethics of making genetic diagnostic inventions available in developing countries, etc.). Similarly, it might have been useful to consider in some greater detail the interaction between patent law and other legal and social systems (eg: research regulation and the operations of solidarity-based institutions) and how those interactions shape both the law and patenting practices.

Ultimately, *Gene Patents and Public Health* is an accessible book from a worthy collection of experts which covers a lot of ground.

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[7] *See* the OECD Guidelines for the Licensing of Genetic Inventions (2006), available at http://www.oecd.org/dataoecd/39/38/36198812.pdf [12 April 2008].

[8] *See* P Drahos, *A Philosophy of Intellectual Property* (Dartmouth: Dartmouth Publishing Group, 1996).